## The Biotechnology Revolution and the Bioweapons Threat

Sandia National Laboratories February 1, 2004

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### **Key Points**

- Biological weapons are growing, strategic international security threat
- BW threat inexorably linked to unstoppable advances in bioscience, biotechnology
- Traditional security strategies will not work for bioweapons
- Elements of international biosecurity strategy



### Bioweapons as Strategic Threat

- Massively lethal, proven to work
- "Reload" potential
- Appeal of asymmetric weapons
  - Knowledge widely dispersed, materials accessible, cheap
  - Dual use hard to track, easily hidden
  - Attribution difficult; little to hold at risk
- Epidemic response systems vulnerable
- Bio S&T advances will drive BW advances

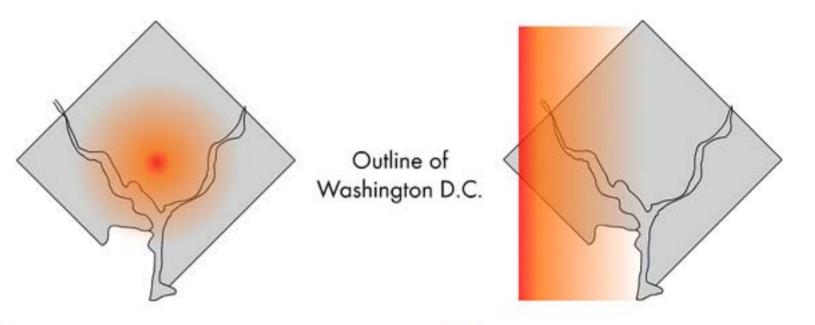


### **Lethality Mirroring Nuclear Weapons**

Congressional Office of Technology Assessment, 1993

1 Megaton Hydrogen Bomb

100 kg of Anthrax Powder







### **Center for Biosecurity**

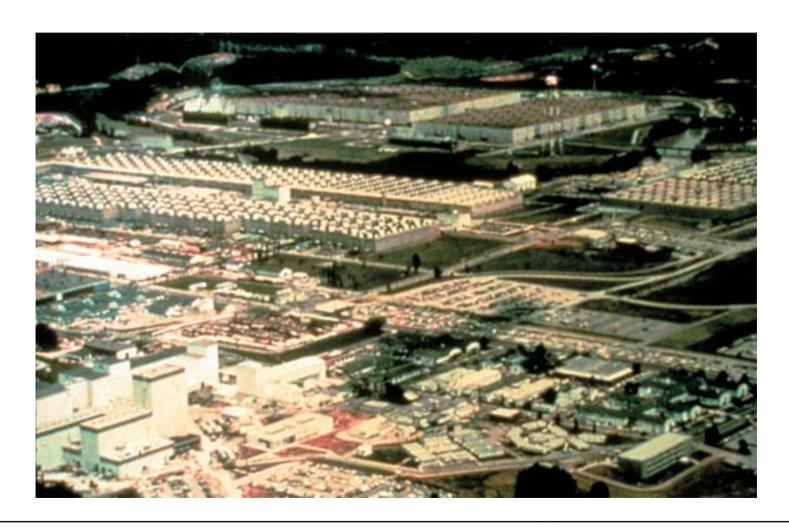


### Bioweapons Program in Iraq





### **Gaseous Diffusion Plant**





### **Bioweapons – Asymmetric Threat**

- Materials and knowledge accessible, widely distributed, dual-use, cheap
- CIA estimates 12 nations possess or are seeking offensive BW capacity
- Can be built and wielded by non-state actors, individuals
- Attribution difficult: no return address



### Consequences of Epidemics

- Not a "lights and sirens event"
- Pervasive uncertainties: scale of attack, location, who is at risk not obvious
- "Reload" potential: multiple attacks possible
- Not over quickly: timeline = months, yrs
- Social, economic disruption may be severe, widespread and sustained
- Burden of response falls on medical, public health communities



### Infectious diseases – a neglected threat





# 21st C: Growing Power of Bioscience, Biotechnology

- Transformative historical moment:
  - building on 20<sup>th</sup> C engineering, computer science
  - genomics; proteomics
  - rational drug discovery
- Global workforce, well capitalized, profit potential
- Scope, speed of advancing knowledge not obvious to many



### Current Reality/Coming Danger

- Lack effective drugs, vaccines for many "20<sup>th</sup> Century" bioweapons agents
- Dual use, 21<sup>st</sup> C technologies can create new pathogens, enhance weaponization
- Novel pathogens easier to create than new countermeasures

### Major Gaps in FDA Approved Countermeasures for Class A Agents

Rapid
Agent Vaccine Therapy Diagnostic

Anthrax	Yes	Yes	No
Smallpox	Yes	No	No
Plague	No	Yes	No
Botulism	No	Limited	No
Tularemia	No	Yes	No
VHF	No	No	No

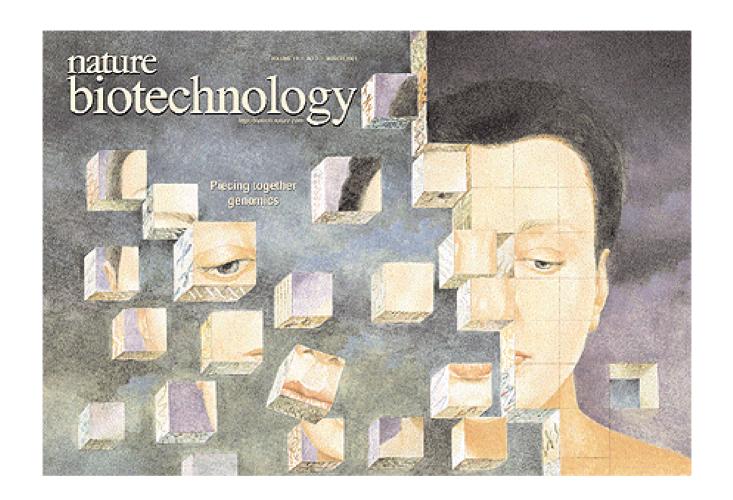
### **Center for Biosecurity**



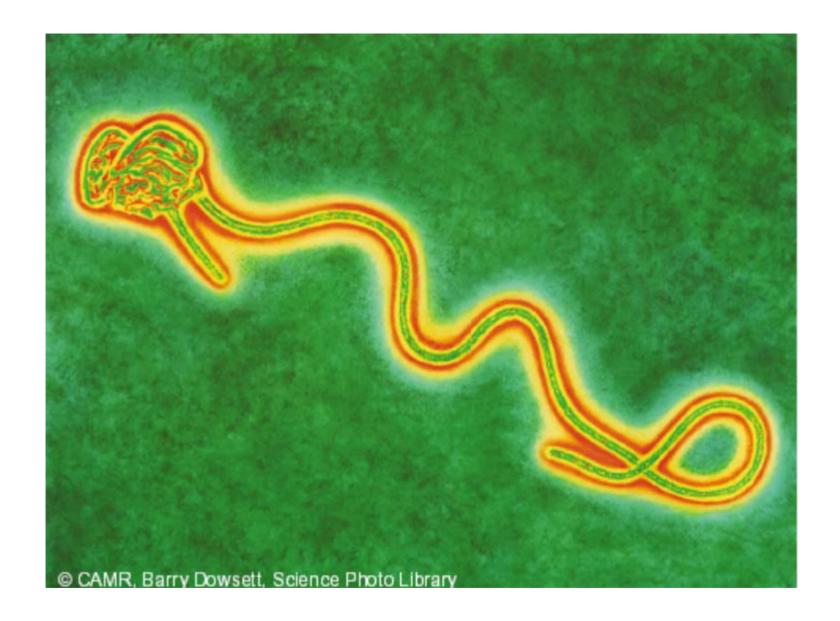
# Advances in Bioscience, Biotechnology: Potential for More Potent Bioweapons

- Enhanced understanding of genomics, biocircuits, etc. present new bioweapons options
- Drug delivery technologies (micorencapsulation, carrier beads, aerosols etc.) can aid weaponization
- As fields advance, technology will become more accessible, simplified
- Huge swath of bioscience, biotech susceptible to dual-use









### **Center for Biosecurity**



### ABI 3900 High-Throughput DNA Synthesizer



REPORTS

# Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template

Jeronimo Cello, Aniko V. Paul, Eckard Wimmer\*

9 AUGUST 2002 VOL 297 SCIENCE www.sciencemag.org





H.L. Ball D.S. King F.E. Cohen S.B. Prusiner M.A. Baldwin Engineering the prion protein using chemical synthesis





Vaccine 19 (2001) 2629-2636



www.elsevier.com/locate/vaccine

A powder formulation of measles vaccine for aerosol delivery

Cynthia LiCalsi \*, Michael J. Maniaci, Troy Christensen, Elaine Phillips, Gary H. Ward, Clyde Witham

Dura Pharmaceuticals, 7475 Lusk Bled., San Diego, CA 92121, USA





#### **Delivery of Biological Agents by Aerosols**

#### David A. Edwards

Div. of Engineering and Applied Sciences, Harvard University, Cambridge, MA 02138

Alkermes, Inc., Cambridge, MA 02139



Figure 2. Commercially available dry powder and metereddose inhalers.

Courtesy of Alkermes, Inc., Cambridge, MA. These inhalers represent portable, handheld, single- or multiple-use inhaler devices for delivering drugs for respiratory disease. New inhalation technology currently in the clinic may employ devices of greater technical sophistication.

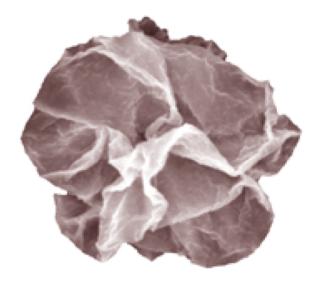


Figure 3. Large (8-µm-dia.) porous drug particle. Courtesy of Dr. Michael Lipp, Alkermes, Inc., Cambridge, MA.





### Dual Use Technologies ???

- DNA shuffling
- Nanopeptide technology
- Combinatorial chemistry
- Microencapsulation
- RNAi
- Viral reverse genetics
- Virus pseudotyping
- Prions
- Biofilms
- Bioregulators

Carrier beads

Cytokines



## Biosecurity: Framing the Challenge

- Bioscientific knowledge not exotic technologies or materials - is key issue
- Dissemination of bioscientific knowledge, biotechnologies is worldwide, unstoppable
- Most bioscience/biotech not owned, controlled by governments
- Restricting access to 20<sup>th</sup> C pathogens is losing game
- "Insider threat" is insignificant compared to opportunities in open literature



## Elements of International Biosecurity Policy

- Biodefense must win: governments should invest heavily in infectious dz R&D, epidemic control capabilities
- Science community must actively participate in biosecurity policy development, enforcement
- The biosecurity problem is global: the solutions must be international



### Invest in Biodefense R&D

- Create international biodefense R&D effort aimed at rendering biological weapons obsolete as weapons of mass lethality – Shift the advantage to the defense
- Near term goal: develop "countermeasures" drugs, vaccines, diagnostics for likely bioweapons
- Long term goal: understand biology of infectious disease, innate immunity, pathogenesis, etc.
- <u>Urgently</u> develop processes, tools to manage epidemics
- Eliminate epidemics of infectious disease within the next quarter century



## Scientific Community Must Lead Quest for Biosecurity

- Raise awareness of biothreat, dual-use problem among university, private sector researchers: recruit leading scientists
- Local review boards, controls more likely to be accepted, efficient
- Nuclear weapons security is not useful model for bioweapons
- Self-defeating strategy: controls that thwart legitimate science, biodefense R&D



## The Problem of Biosecurity is Global

- Very high stakes: global consequences of deliberate pandemic
- How to engage international science community on issues of national security interest?
- How to distinguish offensive v. defensive R&D?
- Bioweapons in hands of non-state actors: international agreements necessary but not sufficient



## **Approaches to International Biosecurity**

- Raise awareness of 21<sup>st</sup> C bioweapons threat among science community worldwide
- Create guidelines for international cooperation during epidemics
  - Harmonize rules for transport, analysis of samples
  - Review process for learning during crises
- Establish process to learn from local efforts to review potentially "dangerous science"



### **Major Challenges**

- How to infuse bioscience expertise into governments' policy decisions
- How to verify compliance with biosecurity provisions
- How to determine attribution for bioattacks
- How to assure biosecurity and progress in bioscience R&D



"Biological scientists have an affirmative moral duty to avoid contributing to the advancement of biowarfare or bioterrorism."

US National Academy of Science "Research in an Age of Terrorism: Confronting the Dual Use Dilemma"



"...the salvation of this human world lies nowhere else than in the human heart, in the human power to reflect, in human modesty, and in human responsibility."

-Vaclav Havel, Washington, DC Feb. 1990



